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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,292	10/18/2001	Lieven Stuyver	09797.0004-00	4833

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EXAMINER
MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/045,292	STUYVER ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *6-34,37,38,43,45-49,52,53 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,35,36,39-42,44,50,51,54-57 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed 7/3/2007 has been received, entered into the record, and carefully considered.

Remarks drawn to rejections of Office Action mailed 1/5/2007 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 1st and 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(b) rejection: which has been changed to a 102(a) rejection.

102(e) rejection: which has been overcome by applicant's arguments.

An action on the merits of claims 1-5, 35-36, 39-42, 44, 50-51, 54-57, and 59 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 7/3/2007 is acknowledged. The traversal is on the ground(s) that the examiner has not demonstrated how the search of the divergent formulas would place an undue burden on him and that all of the compounds used are nucleotides containing a narrow group of bases. This is not found persuasive because the compounds encompass tens of thousands of different compounds. Upon

further review, the examiner actually considered re-instating the original restriction requirement because of the tremendously large group of compounds encompassed by the claims. The only common core among the claimed groups is seen to be a carbon atom, the sugars have divergent moieties in every location, and the only thing common among the bases is that they are attached via a N-atom. Applicant's opinion of what would be burdensome is not seen to be convincing as it relates to the actual amount of time a search of the claims indeed requires.

The requirement is still deemed proper and is therefore made FINAL.

Applicants are required to cancel all claims drawn to a non-elected invention as the rejoinder practice does not apply to the facts in the instant case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-5, 35, 44, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Filippini et al. ("Can HCV affect the efficacy of anti-HIV treatment?, Archives of Virology, 145(5), 937-944, May 2000) is maintained for reasons of record.

It is noted that the examiner does not believe the provisional application 60/241,488, filed 10/18/2000, to completely support the instantly pending claims, as such, the instant claims only obtain the priority date of the provisional application 60/282,156 filed 4/6/2001. Moreover, it is noted that while claims 2-5 limit the compounds used in the method of claim 1, claims 2-5 do not require the compounds limited therein to actually be administered.

Filippini et al. disclose a method of treating patients with HCV compositions comprising Zalcitabine (see 938, "Antiretroviral treatment"), which is known to be 2'-3'-dideoxycytidine, which is a species of the claims rejected above, specifically the compounds of claims 35 and 50 wherein P^1, R^1, and D are all H. Filippini et al. inherently disclose the methods as claimed, as they administer the same compound (Zalcitabine) to the same population, patients with HCV, and thus must have produced the same results.

Applicants argued that the Filippini reference did not qualify as a (b) reference and argued also that it was not an (a) reference. The examiner agrees that this is not a 102(b) reference, but still believes it to be an (a) reference. Applicants argue that "each and every element" is required in the art to be an anticipatory reference. The examiner disagrees. The art discloses a species within the genus of the claims, and a genus claim is anticipated when a species is disclosed in the art. See MPEP 2131.02. A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus. The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Applicants also argue that Filippini administered their drug in combination with another drug to treat a patient infected with HCV and HIV and the combination of drugs produced no effect on HCV-RNA levels. This

is not found convincing. At first, it almost seems that applicants are arguing that their invention may no be enabled, as the art teaches the methods of administering a species within their genus does not affect HCV-RNA levels, which is exactly what applicants are claiming. However, the examiner still believes that the methods claimed are indeed practiced in the art. A species of the genus is administered to a patient with the same disorder. The only step required by applicants invention is "administering to a host in need thereof", which a patient with HCV is.

Claims 1-5, 35-36, 39-42, 44, 50-51, 54-57, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by LaColla et al. (US 6,812,219).

LaColla et al. disclose methods of treating flavivirus or pestivirus infections, including HCV, by administering various modified nucleosides. See compounds VII-XVIII columns 7-11. The art teaches that overlapping compounds are administered to the same population to treat the same disorders. Due to the extremely large genus instantly claimed, it is obvious that the claimed genus is indeed overlapping with the compounds used to treat HCV as set forth in the '219 patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
October 29, 2007

Shaojia A. Jiang
Art unit 1623
Supervisory Patent Examiner

10/29/07